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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,712	01/03/2007	Edouard Guy Stanley	DVCC-009	5098

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EXAMINER
MONTANARI, DAVID A

ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,712	STANLEY ET AL.	
	Examiner	Art Unit	
	David Montanari	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-19,21-25,27 and 33-53* is/are pending in the application.

4a) Of the above claim(s) *12-19,21-25,27 and 33-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/3/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II, claims 12-19, 21-25, 27 and 33-40 in the reply filed on 11/16/2009 is acknowledged.

However, in Applicants response on 11/16/2009, additional claims 41-53 were presented. Applicants request that should the Examiner find that these new claims are in a different group from elected Group II, that they would like to elect newly presented claims 41-53. In response to this, the Examiner does find that newly presented claims 41-53 would constitute a separate and distinct invention from the invention of Group II. Newly presented claims 41-53 are distinct from the invention of Group II, since the method of forming human embryonic stem cell aggregates has distinct and separate uses from the invention of Group II which is drawn a method of generating blood cells. Further both groups can be used separately, since the method of Group II does not require hESC aggregates and the method of claims 41-53 does not require blood cells. Accordingly, in response to Applicants request, claims 41-53 will be examined.

Claims 12-19, 21-25, 27 and 33-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/16/2009.

Claim Objections

Claim 52 is objected to because of the following informalities: in line 1 the word "a" should be replaced with the word "are" since the current recitation of the claim is grammatically incorrect. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 41-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Thomson et al. (US Patent 6,602,711 B1, filed 2/21/2000).

Claim 41 is drawn to a method of forming hESC aggregates using centrifugation.

Claims 42-46 limit claim 41 to dissociated hESC cells, wherein the dissociation is done with trypsin and EDTA.

Claim 50 limits claim 41 to culturing the hESC aggregates to promote growth.

The specification teaches that hESC aggregates encompass embryoid bodies (pg. 1 lines 28-34)

Regarding claims 47-49, which are drawn to centrifugation using low-attachment centrifugation plates or holding vessels, wherein said vessels are round bottom wells or conical shaped wells, these claims are given no patentable weight. The specification merely recites that centrifugation will use these vessels (pg. 11 lines 1-4). There is no teaching in the specification that round or conical-shaped vessels impart any property to the hESC aggregates that would distinguish the hESC aggregates of the claimed method from those taught in the prior art.

Regarding claim 41, Thomson teaches a method of forming ES cells aggregates by obtaining a suspension of ES cells by centrifugation (col. 4 lines 10-13). Thomson continues to teach that their ES cells encompass primate and human (col. 6 lines 11-13 and claim 10).

Regarding claims 42-46, Thomson teaches that to prior to aggregation of ES cells, they are dissociated from adhering to the substrate in clumps using a combination of trypsin and EDTA (col. 2 lines 41-62).

Regarding claim 50, Thomson teaches ES cell aggregates were plated and then seven days layer stained to confirm the existence of cells of the neural phenotype (col. 4 lines 51-53).

Thomson continues to teach that it would be desirable to differentiate hematopoietic cells from the ES cells of their invention (col. 2 lines 13-16).

Thus the cited teachings of Thomson clearly anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 41 and 50-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomson et al. (US Patent 6,602,711 B1, filed 2/21/2000) and Kaufman et al. (2001, PNAS, Vol. 98(19), pgs. 10716-10721).

Claim 51 is drawn to differentiating cells from hESC aggregates.

Claim 52 limits the cells of claim 51 to blood cells.

Claim 53 limits claim 51 to isolating the cultured and/or differentiated hESC's.

Thomson teaches a method of forming ES cells aggregates by obtaining a suspension of ES cells by centrifugation (col. 4 lines 10-13). Thomson continues to teach that their ES cells encompass primate and human (col. 6 lines 11-13 and claim 10). Thomson continues that it would be desirable to differentiate hematopoietic cells from the ES cells of their invention (col. 2 lines 13-16). Thomson does not teach the differentiation of blood cells from hES cells.

However at the time of filing the ordinary artisan would have found it routine and obvious to differentiate and isolate blood cells from hES cells.

Kaufman et al. teach a method of differentiating hematopoietic cells from human ES cells (pg. 10717 col. 2 last parag. bridge pg. 10718 col. 1) with differentiation factors (pg. 10717 col. 1 parag. 4 lines 6-10).

Kaufman teaches that cells were isolated by plucking individual colonies with a pulled Pasteur pipette (pg. 10717 col. 2 parag. 2 lines 1-3).

Kaufman concludes by teaching that "The *in vitro* differentiation of human ES cells provides an opportunity to better understand human hematopoiesis and could lead to a novel source of cells for transfusion and transplantation therapies" (Abstract last sentence).

Thus the ordinary artisan at the time of filing would have found it *prima facie* obvious to combine the teachings of Thomson regarding a method of forming hESC aggregates and desiring to differentiate hematopoietic cells from said hESC aggregates with the teachings of Kaufman regarding the differentiation of hematopoietic cells from hES cells to arrive at the claimed invention of differentiated blood cells from hES cells. One would have been motivated to make

such a combination given the teachings of Thomson that it would be desirable to differentiate hematopoietic cells from hES cells and Kaufman teaching that the *in vitro* differentiation of hematopoietic cells from hES cells could lead to novel sources of cells for transfusion and transplantation therapies. There would have been a reasonable expectation of success that the differentiation of hematopoietic cells from hES cells taught by Kaufman would also differentiate the hES cells of Thomson since they are the same cell type.

Thus the cited art clearly supports a case of *prima facie* obviousness.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is (571)272-3108. The examiner can normally be reached on M-Tr 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Peter Paras, Jr./
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